



A Cross Sectional Study on the Awareness and Participation of the General Population in Clinical Trials

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ABSTRACT

Introduction: In recent years there has been a huge increase in clinical research, enrolling millions of Indians in clinical trials (CTs). The awareness of CTs plays a major role in making the informed decision to participate in CTs.

Aim/Objective: Current study aimed to assess the awareness and perception of Clinical Trials among the General population.

Methodology: A prospective, cross-sectional, questionnaire-based survey was conducted among general public. A pre-validated Questionnaire on the awareness of Clinical trials was used.

Results: Overall 83.9% of the participants were aware of Clinical trials. Among 283 responders 51.24% were male. Among the general public, interestingly 52.65% of the participants knew about CTs before Covid. 77.38% believed that clinical trials are needed for society, however, 38.52% thought there's risk involved in participating in a CTs, and 39.93% believed family/relative will allow them to participate in the study. Majority of the participants (84.45%) accepted that CTs are needed for the advancement of knowledge. Majority of the participants were aware that the risks and benefits of CTs will be mentioned clearly (61.23%) and 80.92% aware permissions/approvals needed for conducting any CTs. Nearly 47.70% are aware that anyone who is found eligible for the CT can participate (53%). However, more than half of the study population (52.30%) were anxious about the side effects.

Conclusion: The current study data suggested that there is a lack of particular understanding about clinical trials among the general people. There is a need to raise awareness of Clinical Trials among the general public.

Key Words: Clinical Trials (CTs), Human Participants, Knowledge, Awareness, General public, Perception

INTRODUCTION

A clinical trial is a type of study that is carried out on human participants to determine the pharmacokinetic parameters, safety, and effectiveness of a novel investigational treatment, procedure, or equipment. There is currently a paradigm shift in the clinical trials market. The market for clinical trials is expanding throughout developing countries due to a naïve diversified patient population. Major pharmaceutical companies are directing their investment towards developing countries due to their speedier go-to-market. In addition, the Pharma-Biotech industry's stringent regulations and limited R&D budgets are driving businesses to relocate to the East. The ties between clinical research organizations (CROs) and PharmaBiotech have been strengthened by this scenario,

as the CROs are responsible for a significant portion of the studies carried out.¹

In the last decade, there has been a sharp increase in the need for top-notch clinical trial management productivity and capacity worldwide. The international biopharmaceutical sector finds India's pool of highly skilled doctors, trained medical personnel, investigators, and the support research infrastructure to be highly attractive.² One of the most significant obstacles researchers encounter when conducting Clinical Trials (CTs) is recruiting and retaining a sufficient number of participants, which is necessary for an effective CT.³ Participation of human subjects in clinical trials are one of the leading challenges faced by researchers. In spite of the positive attitudes, participants in survey

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conducted had relatively little awareness and only 31.3% of individuals were aware about Clinical Trial.⁴ The majority of the population is unaware of the clinical trial and regulatory requirements for the informed consent document.⁵ None of them are aware of their rights to professional competence, privacy, integrity, transparency, non-exploitation, and non-usage of their biological samples.⁶

The main factor affecting participation is the level of trust in the research entity and the researcher. Safety issues like adverse drug reactions were also perceived as an important factor.⁷ Education level affects public attitude; studies have found that people with biomedical degrees are more willing to participate when compared with other groups.⁸ Nedal et al.'s 2019 study revealed that survey participants' attitudes and mean scores regarding Clinical Trials were poor. Additionally, the finding highlighted that while the majority of participants believed that CTs could be used on patients, only 30.5% agreed that CTs could be used to introduce new medications and other interventions to healthy individuals.⁹ In a recent survey evaluating general public knowledge and attitudes regarding CTs only 7.0% of the participants were aware of ClinicalTrials.gov, and 43.1% had no knowledge of CTs at all.¹⁰ People at times are unsatisfied with and mistrustful of the way clinical trials are conducted while few have no knowledge of clinical trials. Therefore, more efforts are needed to enhance their understanding towards the conduct of Clinical Trials. The assessment of the general population's knowledge and attitude towards CTs will help us to remove the misconceptions about CTs by increasing their knowledge according to the knowledge gap on CTs. The present study aimed to access the awareness and perception of Clinical Trials among the General population.

METHODOLOGY

A prospective cross-sectional, observational, questionnaire-based survey was conducted among the general public, aged above 18 years. Of 348 responses, 337 responses who were willing to participate in the study were included in the study, who were aged above 18 years, and who could read and write English were included in the study. Meanwhile, study subjects who were not willing to participate and those with diminished linguistic ability were excluded from the study.

The survey used a prevalidated Questionnaire on the awareness of Clinical trials. The survey was carried out by using self-administered questionnaires using Google Forms and was shared through various social media platforms and the data collected were analyzed. The study was approved by the Institutional Ethics Committee, Apollo Hospitals, Chennai.

The questionnaire consists of the following sections: the first section includes consent, demographic details which included age, gender, educational qualification occupation. The

form had 5 categories: consent, demographic characteristics, basic knowledge of Clinical Trials, Public opinion, and Perception about Clinical trials. Before completing the survey, participants had to provide their consent through the same Google form. The baseline characteristics of the participants were presented as frequency and percentages. The data was analysed using SPSS version 22.0 (IBM). P value ≤ 0.05 was considered statistically significant for all analyses.

RESULTS

Of the total 337 respondents who started filling out the questionnaires, 83.9% (n=283) were aware of Clinical Trials (83.9%) and responded to the awareness questionnaire and, completed the whole survey, which was considered for the statistical analyses.

Among 283 responders 51.24% (145) were male and 48.76% were female (138), 52.3% were undergraduates, 36.75 % had a postgraduate degree and 10.95% had completed only schooling. Looking into their educational background with reference to their majors, 67.5% of the study participants belonged to a biological stream while 32.53% belonged to the non-biological streams like arts and commerce. Based on their occupation, 46.64% of the study participants were employed, 31.45% were students, 8.48% were unemployed, 7.42% were homemakers and 6.01% were in business (Table 1). In terms of awareness of clinical trials among the general public, interestingly 52.65% of the participants knew about CTs even before Covid and attributed their knowledge in CTs to social media/internet (30.74%), relatives/friends (30.74%) news (13.78%), and other informative sources (24.73%). On the other hand, 47.35% knew about clinical trials only after the Covid breakout (Table 2).

Table 3 shows the awareness and perception of clinical Trials among the general public. It was an interesting finding that 77.38% of the participants believed that clinical trials are needed for society and 84.45% of the participants think Clinical Trials are needed for the advancement of knowledge. 72.44% believed that stringent laws were required by the government for the conduct of the CT, 68.90% thought that new medicines can come to market only through clinical trials and 50.88% would recommend to friends/ relatives to participate in clinical trials. However, 38.52% think there's risk involved in participating in a clinical trial, only 39.93% believed that their family/relative will allow them to participate in the study even if they wished to and 21.20% believed the clinical trial would disturb their daily routine.

About 69.2% of participants were aware that participation in clinical trials is voluntary, and healthy people can participate in Clinical trials (69.61%). Further participants were aware that the risks and benefits of the clinical trials will be mentioned clearly (61.23%) and permissions/approvals needed

for conducting any Clinical Trials (80.92%). The majority of the study population was aware that Clinical Trial improves the lives of other patients (79.15%). Nearly 47.70% are aware that anyone who is found eligible for the clinical trial can participate and Trial participants get the best supportive care (53%). However, more than half of the study population (52.30%) were anxious about the Side effects.

Table 1: Demographic details of the study population.

Variables		N (%)
Gender	Male	145 (51.24%)
	Female	138 (48.76%)
Educational Status	Post Graduates	104 (36.74%)
	Graduates	148 (52.29%)
	School competeion	31 (10.95%)
Educational background	Biological stream	170 (67.5%)
	Non-Biological (Arts & Commerce) stream (252)	82(32.53%)
Occupation	employed	132(46.64%)
	Students	89 (31.45%)
	Unemployed	24 (8.46%)
	Homemaker	21 (7.42%)
	Business	17 (6.01%)

Table 2: General Awareness of Clinical trails

Variable	N (%)
How did you come to know about Clinical Trials?	Social media/internet
	Relatives/ friends
	News
	Other sources
When did you come to know about Clinical Trials?	Before Covid Pandemic
	During Covid Pandemic

Table 3: Awareness and perception of clinical trials among general public

S. No.	Questions	Yes	No	Maybe
1	Are clinical trials needed for the society	77.38%	3.89%	18.73%
2	Can healthy people participate in Clinical Trial?	69.61%	4.24%	26.15%
3	Do you think participation in Clinical trial is voluntary?	69.26%	9.54%	21.20%
4	Is there risk involved in participating in a clinical trial?	38.52%	19.78%	41.70%

5	Are risk and benefits clearly mentioned for a clinical trial?	61.13%	6.36%	32.51%
6	Are permissions/approvals needed for conducting CTs	80.92%	4.59%	14.49%
7	Do you think CTs are needed for advancement of knowledge?	84.45%	2.12%	13.43%
8	Will you recommend your friends/ relatives to participate in clinical trials?	50.88%	12.02%	37.10%
9	Do you think CT helps and improves the life of other patients?	79.15%	4.24%	16.61%
10	Will your family/relative allow you to participate in the study if you wish to?	39.93%	21.55%	38.52%
11	Do you feel clinical trial would disturb your daily routine?	21.20%	32.86%	45.94%
12	Are you anxious about the Side effects?	52.30%	17.67%	30.03%
13	Anyone found eligible can be a trial participant?	47.70%	17.32%	34.98%
14	Trial participants get the best supportive care	53%	6.36%	40.64%
15	New medicines can come to market only through clinical trials	68.90%	5.30%	25.80%
16	Are stringent Rules and regulations required to govern the conduct of clinical trials	72.44%	4.24%	23.32%

DISCUSSION

Awareness in clinical research represents the level of understanding and knowledge that people have about clinical research, its purpose, process, and benefits. The cost, effectiveness, and quality of our healthcare system are directly impacted based on the information from clinical research. There is an increasing demand for clinical research to generate high-quality data and expedite the transfer of breakthroughs from basic science to clinical treatment and ultimately to improved health. Adhering to the highest standards when conducting clinical trials has led to the creation of several novel medicines that have greatly enhanced patient outcomes.^{11,12} As per the current regulations in India, pharmaceuticals can only be tested on Indians if they have completed Phase 1 safety testing in their home country.

To take part in CTs, the population must have a positive attitude. It might motivate people to take part in CTs. Moreover, an positive attitude spreads among other family and community members similarly to illnesses.^{13,14} Inline with this, the current study finding highlighted that the majority of participants (77.38%) believed that clinical trials are needed for

society and 84.45% of the participants thinks Clinical Trials are needed for the advancement of knowledge. In terms of gender and age, youngsters and men are more willing to participate compared with older adults and women.¹⁵ All important improvements in patient engagement should be based on a deep understanding of public and patient attitudes, perceptions, and observations in clinical research.¹⁶ Early good experiences with clinical trials will enhance the chance of human participation in future studies.¹⁷

Perhaps current finding also throw light on the certain aspect of perception among general population about the risk involved (38.52%) in participating in a clinical trial, and based on that the more than 60% of the participants believed that their family/relative will not allow them to participate in the study even if they wished to. A few studies reported a moderately positive attitude towards CTs.¹⁸⁻²¹ This indicates that a poor attitude towards participating in CTs is a global phenomenon and needs immediate attention from stakeholders.

However, the current survey has some limitations. First, we applied a questionnaire-based cross-sectional design, and the constraints related to this design must be considered while interpreting the findings of the current survey, such as recall bias and exaggerated responses. Next, we utilized a snowball sampling method. Hence, the possibility of selection bias cannot be avoided. In addition, due to the wide sociocultural variation across the country, the present research findings cannot be generalized to the entire Indian general population. However, the general population is not aware of the option or the opportunity to participate in clinical trials. This can limit the number of people who enroll in clinical trials and affect the generalizability and applicability of the research results. Given the limitations of the current study, we recommend using mixed-methods exploratory surveying to identify the need for health education focused on Clinical Trials.

CONCLUSION

The present study revealed a positive trend towards increasing awareness about clinical trials. To understand the underlying factors that contribute to the differences in clinical trial knowledge and awareness, larger studies on individuals from various strata are needed. It is important to raise awareness and educate the public, patients, and health care providers about clinical trials and how they can get involved. Some of the ways to enhance public awareness of clinical trials are using plain language and clear communication to explain what clinical trials are, how they work, what are the potential benefits and risks, and what are the rights and responsibilities of participants. Sharing information and resources about clinical trials through various channels, such as websites, social media, newsletters, brochures, flyers, posters, videos, podcasts, etc, will increase participation.

Future research can focus on increasing public awareness and the significance of Clinical Trial participation. This can be accomplished by implementing focused health education initiatives in various public spaces. The general public's attitudes and views of CTs would be improved by such health education initiatives, which would be beneficial for the development of novel drugs. Awareness in clinical trial is the degree to which patients and health care providers are informed about the existence, purpose, and benefits of clinical trials. Clinical trials can help improve the quality of life and outcomes for patients, as well as advance medical knowledge and innovation. Hence, it is important for the general population to be informed about the existence, purpose, and benefits of clinical trials.

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